III. Specification Amendments

(¶ on page 42 beginning on line 8)

The mutant produced as described, was tested for its ability to replicate *in vitro*, a requirement for large-scale vaccine production. FEK cells and the ED cell line were transfected with the EIAV$_{PR}$ΔDU as described previously in Example 2. It was determined that the RT activity was equal to that of wild-type EIAV$_{UK}$. However, when equine macrophage cultures were ~~transfected~~ infected with this construct at a multiplicity of infection (MOI) of 0.01, very little replication (as measured by RT activity) was noted. This suggests that such a construct would replicate poorly if at all in horses. The tissue culture grown proviral construct was confirmed to be EIAV$_{PR}$ΔDU by RT-PCR. These experiments determined that EIAV$_{PR}$ΔDU could be produced *in vitro* in large scale in either FEK or ED cells.

In order to determine whether a vaccine could be prepared and whether such a vaccine would protect horses from disease and/or infection, the ED cell line was transfected and a large quantity of EIAV$_{PR}$ΔDU was produced. In this study, the ~~proviral~~ vaccine construct was inactivated by addition of 0.1% formalin and adjuvanted with a polymer-based adjuvant, specifically with a Carbopol-based adjuvant designated HAVLOGEN®. Two vaccines were formulated. One contained 50µg/dose (1.0 mL) while the second contained 10µg/dose Each of three horses received 3 doses of 50µg/dose vaccine and each of three horses received 3 doses of 10µg/dose vaccine . The interval between vaccinations was one month. Three additional horses were left unvaccinated and served as negative controls. Nine weeks post final vaccination, all horses were challenged with a multiple low dose challenge using EIAV$_{PR}$, a heterologous strain. This constituted administering 10 MHIDs three times over a 7 day period (days 0, 2 and 5).

Horses were monitored for temperature, platelet count, plasma viremia and seroconversion for 7 weeks post challenge. Results of this vaccination/challenge study are shown in Table 4.